The **Electronic Common Technical Document (eCTD)** is the standard format for submitting applications, amendments, supplements, and reports to FDA’s Center for Biologics Evaluation and Research (CBER) and Center for Drug Evaluation and Research (CDER).

An eCTD submission has five modules: region-specific information, summary documents, quality-related information, nonclinical study reports, and clinical study reports.

When materials are submitted electronically, it is easier for FDA to review data, approve new drugs, and monitor drugs after they go on the market. Using eCTD also simplifies the process for submitters, because it is the same format used by drug regulatory agencies in other countries.

Starting in 2017, **eCTD will be required for submissions to CBER and CDER. After the dates listed below, submissions that are not in eCTD format will not be filed or received unless exempted from the requirement.**

Electronic submissions must include **only** FDA fillable forms (e.g., 1571, 356h) and electronic signatures to enable automated processing of the submission. The most current FDA forms are available at [www.fda.gov/AboutFDA/ReportsManualsForms/Forms](http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms). Scanned images of FDA forms will **not** be accepted.

**Deadlines**

- **NDAs, ANDAs, and BLAs**, as of **May 5, 2017**, must be submitted using the eCTD standard.
- **INDs and MFs**: as of **May 5, 2018**, must be submitted using the eCTD standard.

Updates to the standard will be announced on the FDA website and published in the Federal Register.

**Additional information**

Visit [www.fda.gov/ectd](http://www.fda.gov/ectd) to find all of the relevant guidances and technical specifications for eCTD and a step-by-step guide to setting up an Electronic Submissions Gateway account.

For additional questions, please contact CBER at esubprep@fda.hhs.gov or CDER at esub@fda.hhs.gov.